

**Response Under 37 CFR 1.116
Expedited Procedure
Examining Group 1744**

Appl. No. 10/840,178
Amdt. AF dated February 28, 2006
Reply to final Office Action of November 28, 2005
Attorney Docket No. 2034-044072

REMARKS

Claims 20-27 and 29-38 were pending in this application. New claims 39-47 are added. No new subject matter is believed to have been added by these amendments. Therefore, claims 20-27 and 29-47 remain in this application.

Specification Objections

The specification stands objected to because the Examiner contends that essential material in the specification has been improperly incorporated into the specification by reference to a publication. Specifically, the Examiner points to the last line of paragraph [0036] on page 9. Applicants do not believe that essential material has been incorporated into the specification by this portion of the specification. The Maeda et al. article and the Kinoshita et al. article mentioned in the last line of paragraph [0036] only provide examples of membranes that are responsive to changes in pH. Since the claims only require that the separation barrier be selected from the group consisting of a fibril membrane, a microporous membrane and a capillary-pore membrane, Applicants believe that no essential subject matter has been incorporated by reference to the Maeda et al. article and the Kinoshita et al. article. Accordingly, Applicants respectfully request reconsideration and withdrawal of this objection.

35 U.S.C. § 112 Rejections

Claims 20, 21, 26, 27 and 29-38 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner believes that Applicants are relying on the Maeda et al. article and the Kinoshita et al. article for support of the language of claim 20 describing the separation barrier as “having at least one pore allowing fluid communication between the interior and exterior of the sensor compartment”. However, support for the preceding language can be found throughout the

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specification as originally filed. For example, support for such language can be found in paragraph [0033] which provides that “the gated-pores open allowing water to par through the membrane and into the detector compartment” and claim 1 as originally filed which provides for “a separation barrier ... having at least one pore allowing fluid communication between the interior and exterior of the biosensor enclosure”. Accordingly, the Applicants believe that the language “having at least one pore allowing fluid communication between the interior and exterior of the sensor compartment” is fully supported by the specification and claims as originally filed.

Reconsideration and withdrawal of this rejection are respectfully requested.

Claim Objections

Claims 22-25 are objected to under 37 C.F.R. § 1.75(c) as being of improper dependent form since they do not include all the limitations of the independent claim. Specifically, the Examiner contends that claims 22-25 do not include the limitation of having “at least one pore allowing fluid communication between the interior and exterior of the sensor compartment”. Applicants do not agree with the Examiner’s objection. The test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends or in other words that it shall not conceivably be infringed by anything which would not also infringe the basic claim. Claim 22 includes each and every limitation of the claim from which it depends (i.e., independent claim 20). Although claim 22 requires that the at least one pore is occluded with a responsive material, this occlusion does not prevent the at least one pore from allowing fluid communication between the interior and exterior of the sensor compartment. The specification clearly describes that the responsive material exhibits a response such as erosion or dissolution thereby allowing fluid communication (see paragraph [0032]).

Accordingly, reconsideration and withdrawal of this objection are respectfully requested.

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35 U.S.C. § 103 Rejections

Claims 20-27, 29, 30 and 36-38 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of United States Patent No. 6,315,767 to Dumont et al. (hereinafter “the Dumont patent”) and United States Patent No. 5,164,796 to Di Guiseppi et al. (hereinafter “the Di Guiseppi patent”). In view of the following remarks, the Applicants respectfully request reconsideration of this rejection.

As defined by independent claim 20, the present invention is directed to a sensor device comprising a biosensor including a receptor bound on a solid substrate, a sensor compartment having an interior and an exterior and enclosing the biosensor, and a separation barrier forming at least a portion of the sensor compartment. The sensor compartment has a surface allowing external viewing of the biosensor. The separation barrier is selected from the group consisting of a fibril membrane, a microporous membrane and a capillary-pore membrane. The separation barrier also has at least one pore allowing fluid communication between the interior and exterior of the sensor compartment.

The Dumont patent is directed to a device with a membrane having a plurality of pores filled with an erodible substance responsive to selected characteristics of blood in a bag containing the device. More particularly, the Dumont patent teaches that the pores are preferably filled with an erodible substance (24) which is responsive to, and erodible upon exposure to, certain environmental conditions or a selected characteristic of a blood product (26) contained within the inner volume of the bag (12), such as a pH level or decreased glucose level (see column 4, lines 12-16). The Dumont patent further discloses that the erodible substance (24) contained within the pores (22) begins to dissolve when the pH of the stored blood product drops to 6.4 and is completely eroded away when the pH of the blood product reaches 6.2 (see column 4, lines 24-31).

The Dumont patent fails to teach or suggest that the membrane may be composed of a material responsive to a selective characteristic of the blood product, such that the unfilled pores themselves are responsive to the selected characteristic, having a relatively smaller pore size at a first value of the selected characteristic and a relatively larger pore size

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at a second value of the selected characteristic (see column 2, line 65 to column 3, line 4). Even in the aforementioned contemplated membrane configuration taught by the Dumont patent, the membrane is required to be actively responsive to a selected characteristic of blood in a blood bag.

Further, the Dumont patent fails to teach or disclose a separation barrier forming a portion of the sensor compartment, wherein a separation barrier selected from the group consisting of a fibril membrane, a microporous membrane and a capillary-pore membrane as required by independent claim 20. Additionally, the Dumont patent fails to teach or suggest a biosensor comprising a receptor bound on a solid substrate as also required by independent claim 20.

The Di Giuseppe patent is directed to an instrument for monitoring the color change of an indicator element sealed within a sterile vessel, and is provided by the Examiner as a teaching of the use fluorescent-receptor complex pH indicators bound to a solid support for fluorescent detection of changes in pH. The Di Giuseppe patent fails to teach or suggest a separation barrier selected from the group consisting of a fibril membrane, a microporous membrane and a capillary-pore membrane as required by independent claim 20. Additionally, the Di Giuseppe patent fails to teach or suggest a biosensor comprising a receptor bound on a solid substrate as also required by independent claim 20. Accordingly, the Di Giuseppe patent does not cure the deficiencies of the Dumont patent as presented above.

For the foregoing reasons, the Applicants believe that the subject matter of independent claim 20 is not rendered obvious by the Dumont patent in view of the Di Giuseppe patent. Reconsideration of the rejection of claim 20 is respectfully requested.

Claim 21-27, 29, 30 and 36-38 depend from and add further limitations to independent claim 20 and are believed to be patentable for the reasons discussed hereinabove in connection with independent claim 20. Reconsideration of the rejections of claims 21-27, 29, 30 and 36-38 is respectfully requested.

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The Examiner has also rejected claims 20-26, 29, 31 and 36-38 under 35 U.S.C. § 103(a) as being obvious in view of the Dumont patent and United States Patent No. 6,210,910 to Walt et al. (hereinafter "the Walt patent").

The Dumont patent was discussed hereinabove in connection with independent claim 20. The Walt patent is directed to a biosensor array that utilizes an optically interrogatable encoding scheme for determine the identity and location of different cell types, and is provided by the Examiner as a teaching of the use of fluorochrome-receptor complexes for determining cell viability. The Walt patent does not cure the deficiencies of the Dumont patent.

For the foregoing reasons, the Applicants believe that the subject matter of independent claim 20 is not rendered obvious by the Dumont patent in view of the Walt patent. Reconsideration of the rejection of claim 20 is respectfully requested.

Claim 21-26, 29, 31 and 36-38 depend from and add further limitations to independent claim 20 and are believed to be patentable for the reasons discussed hereinabove in connection with independent claim 20. Reconsideration of the rejections of claims 21-26, 29, 31 and 36-38 is respectfully requested.

New Claims

New claims 39-47 have been added by this Amendment. New claim 39 is independent, and new claims 40-47 depend therefrom. No new matter was added. Support for new claim 39-47 can be found in the specification and drawings as originally filed. Claim 39-47 are also believed to be allowable over the prior art of record.

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CONCLUSION

Based on the foregoing amendments and remarks, reconsideration of the rejections and allowance of pending claims 20-27 and 29- are respectfully requested.

Respectfully submitted,

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